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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION,	:	Honorable Susan D. Wigenton, U.S.D.J.
Plaintiff,	:	Civil Action No. 07 CV 286 (SDW)(MCA)
v.	:	
BARR LABORATORIES, INC.,	:	
Defendant.	:	

CELGENE CORPORATION and CHILDREN'S MEDICAL CENTER CORPORATION, ,	:	Honorable Susan D. Wigenton, U.S.D.J.
	:	Civil Action No. 08 CV 3357 (SDW)(MCA)
Plaintiffs,	:	
v.	:	**DEFENDANT BARR LABORATORIES, INC.'S ANSWER, COUNTERCLAIMS AND DEMAND FOR JURY TRIAL**
BARR LABORATORIES, INC.,	:	
Defendant.	:	

Defendant Barr Laboratories, Inc. ("Barr Laboratories"), by and through the undersigned attorneys, answers the Complaint of Plaintiffs Celgene Corporation ("Celgene") and Children's Medical Center Corporation ("CMCC") as follows:

Nature of the Action

COMPLAINT:

1. This is an action for patent infringement under the patent laws of the United States, 35 United States Code, arising from Barr Laboratories, Inc.'s filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Celgene's Thalomid® prior to the expiration of certain patents owned by CMCC and exclusively licensed to Celgene that cover that product's use, *i.e.*, United States Patent Nos. 5,629,327 (the "'327 patent") and 6,235,756 (the "'756 patent") (collectively, "the patents-in-suit").

RESPONSE : Barr Laboratories admits that Plaintiffs' complaint is for patent infringement, but denies that Plaintiffs are entitled to the requested relief. Barr Laboratories further admits that it filed with FDA ANDA No. 78-505 seeking approval to market a generic version of Thalomid® prior to the expiration of U.S. Patent Nos. 5,629,327 (the "'327 patent") and 6,235,756 (the "'756 patent"), among others. Barr Laboratories further admits that the face of the '327 patent lists Childrens Hospital Medical Center Corp. as assignee, and the face of the

'756 patent lists The Children's Medical Center Corporation as assignee. Barr Laboratories is without knowledge or information sufficient to form a belief as to the truth of whether Celgene is an exclusive licensee of the '327 and '756 patents and therefore denies the same. Barr Laboratories denies the remaining allegations of paragraph 1.

The Parties

COMPLAINT:

2. Plaintiff Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

RESPONSE : Barr Laboratories admits the allegations of paragraph 2, on information and belief.

COMPLAINT:

3. Plaintiff CMCC is a Massachusetts not-for-profit corporation, having a principal place of business at 55 Shattuck Street, Boston, Massachusetts 02115. CMCC is the sole member of Children's Hospital Boston, also a Massachusetts not-for-profit corporation and the primary pediatric teaching hospital of Harvard Medical School.

RESPONSE : Barr Laboratories admits that Plaintiff CCMC has an address at 55 Shattuck Street, Boston, Massachusetts 02115, on information and belief. Barr Laboratories is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 3 and therefore denies the same.

COMPLAINT:

4. On information and belief, defendant Barr Laboratories, Inc. is a corporation, having its principal place of business at 223 Quaker Road, Pomona, New York 10970.

RESPONSE : Barr Laboratories admits the allegations of paragraph 4.

COMPLAINT:

5. On information and belief, defendant Barr Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

RESPONSE : Barr Laboratories states that Barr Pharmaceuticals, Inc. is no longer a party to this action by the parties' stipulation and therefore is not a "defendant." Barr Laboratories admits that Barr Pharmaceuticals maintains a place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677, but further states that it has moved its corporate headquarters to 225 Summit Avenue, Montvale, NJ 07645**.**

COMPLAINT:

6. On information and belief, defendant Barr Laboratories, Inc. is a subsidiary of defendant Barr Pharmaceuticals, Inc.

RESPONSE : Barr Laboratories states that Barr Pharmaceuticals, Inc. is no longer a party to this action by the parties' stipulation and therefore is not a "defendant." Barr Laboratories admits the remaining allegations of paragraph 6.

COMPLAINT:

7. On information and belief, Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. are registered to do business in New Jersey. Further, on information and belief, Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. maintain executive offices and a manufacturing facility and otherwise transact business within this District.

RESPONSE : Barr Laboratories admits that Barr Laboratories and Barr Pharmaceuticals, Inc. are registered to do business in New Jersey and maintain executive offices within this District. Barr Laboratories denies that Barr Laboratories and Barr Pharmaceuticals, Inc. maintain a manufacturing facility in this District. Barr Laboratories further states that it is without knowledge or information sufficient to form a belief as to the truth of the allegation that Barr Laboratories and Barr Pharmaceuticals, Inc. "otherwise transact business within this District" because the phrase is vague and undefined in context and therefore denies the same.

COMPLAINT:

8. On information and belief, the acts of Barr Laboratories, Inc. complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least in part for the benefit of, Barr Pharmaceuticals, Inc.

RESPONSE : Barr Laboratories states that it is without knowledge or information sufficient to form a belief as to the truth of the allegation that the acts of Barr Laboratories "were done . . . at least in part for the benefit of" Barr Pharmaceuticals, Inc. because the phrase is vague and undefined in context, and therefore denies same. Barr Laboratories denies the remaining allegations of paragraph 8.

COMPLAINT:

9. Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. are referred to hereinafter, collectively, as "Barr."

RESPONSE : Paragraph 9 is a characterization of Celgene's Complaint, and contains no allegations of fact to which an answer is required.

Jurisdiction and Venue

COMPLAINT:

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

RESPONSE : Paragraph 10 contains conclusions of law for which no response is required. To the extent a response is required, Barr Laboratories admits that this Court has subject matter jurisdiction over Celgene's claims against Barr Laboratories under 28 U.S.C. §§ 1331 and 1338(a). Barr Laboratories denies the remaining allegations of paragraph 10.

COMPLAINT:

11. This Court has personal jurisdiction over Barr by virtue of the fact that Barr has availed itself of the laws of New Jersey and conducts business in New Jersey.

RESPONSE : Paragraph 11 contains conclusions of law for which no response is required. To the extent a response is required, Barr Laboratories admits that this Court has personal jurisdiction over it. Barr Laboratories denies the remaining allegations of paragraph 11.

COMPLAINT:

12. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

RESPONSE : Paragraph 12 contains conclusions of law for which no response is required. To the extent a response is required, Barr Laboratories admits the allegations of paragraph 12.

The Patents in Suit

COMPLAINT:

13. On May 13, 1997, the USPTO duly and lawfully issued the '327 patent, entitled "Methods and Compositions for Inhibition of Angiogenesis" to CMCC as assignee of the inventor Robert D'Amato. A copy of the '327 patent is attached hereto as Exhibit A.

RESPONSE : Barr Laboratories admits that the PTO issued the '327 patent on May 13, 1997, and that it is entitled "Methods and Compositions for Inhibition of Angiogenesis." Barr Laboratories further admits that Robert D'Amato is listed as the inventor on the face of the '327 patent and that the PTO lists Childrens Hospital Medical Center Corp. as the assignee. Barr Laboratories denies that the '327 patent was duly or lawfully issued. Barr Laboratories is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 13 and therefore denies the same.

COMPLAINT:

14. On May 22, 2001, the USPTO duly and lawfully issued the '756 patent, entitled "Methods and Compositions for Inhibition of Angiogenesis by Thalidomide" to CMCC as assignee of the inventor Robert D'Amato. A copy of the '756 patent is attached hereto as Exhibit B.

RESPONSE : Barr Laboratories admits that the PTO issued the '756 patent on May 22, 2001, and that it is entitled "Methods and Compositions for Inhibition of Angiogenesis by Thalidomide." Barr Laboratories further admits that Robert D'Amato is listed as the inventor on the face of the '756 patent and that the PTO lists The Children's Medical Center Corporation as the assignee. Barr Laboratories denies that the '756 patent was duly or lawfully issued. Barr

Laboratories is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 14 and therefore denies the same.

COMPLAINT:

15. Celgene is an exclusive licensee under the '327 and '756 patents.

RESPONSE : Barr Laboratories is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 15 and therefore denies the same.

The THALOMID® Drug Product

COMPLAINT:

16. Celgene holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a) for thalidomide capsules (NDA No. 20-785), which it sells under the trade name THALOMID®. The claims of the '327 and '756 patents cover methods of treatment by administering compositions containing thalidomide.

RESPONSE : Barr Laboratories admits that FDA lists Celgene as the holder of approved NDA No. 20-785, for thalidomide capsules that Celgene sells as Thalomid®. Barr Laboratories denies the remaining allegations of paragraph 16.

COMPLAINT:

17. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '327 and '756 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to THALOMID®.

RESPONSE : Barr Laboratories admits that Celgene caused the '327 and '756 patents, among others, to be listed in the Orange Book in connection with Thalomid®. Barr Laboratories denies the remaining allegations of paragraph 17.

Acts Giving Rise to this Suit

COMPLAINT:

18. Pursuant to Section 505 of the FFDCA, Barr filed ANDA No. 78-505 and amendments thereto for thalidomide capsules, seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of thalidomide capsules 50 mg, 100 mg, 150 mg, and 200 mg ("Barr's Proposed Products"), before the patents-in-suit expire.

RESPONSE : Barr Laboratories admits that it filed ANDA No. 78-505 under 21 U.S.C. § 355(j) and currently seeks FDA approval to engage in the commercial manufacture, use and sale of thalidomide capsules, 50 mg, 100 mg, and 200 mg, prior to expiration of the '327 and '756 patents, among others. Barr Laboratories further states that it has withdrawn its ANDA amendment seeking approval for 150 mg capsules. Barr Laboratories denies the remaining allegations of paragraph 18.

COMPLAINT:

19. In connection with the filing of its ANDA as described in the preceding paragraph, Barr has provided written certifications to the FDA, as called for by Section 505 of the FFDCA, alleging that the claims of the '327 and '756 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Barr's ANDA.

RESPONSE : Barr Laboratories admits that, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), Barr Laboratories submitted to FDA "paragraph IV" certifications to the '327 and '756 patents, among others, stating that those patents are invalid, unenforceable, and/or will not be infringed by Barr Laboratories' ANDA products. Barr Laboratories denies the remaining allegations of paragraph 19.

COMPLAINT:

20. On May 21, 2008, Barr amended its ANDA to seek approval to engage in the commercial use, manufacture, sale, offer for sale or importation into the United States of Barr's Proposed Products before the '327 and '756 patents expire. The '327 and '756 patents were listed in the Orange Book prior to Barr's filing of its ANDA. After amending its ANDA, Barr was required to send Celgene and CMCC notification pursuant to 21 U.S.C. § 355(j)(2)(B)(ii).

RESPONSE : Barr Laboratories admits that, pursuant to 21 U.S.C. § 355(j)(1), Barr's ANDA was amended to include "paragraph IV" certifications to the '327 and '756 patents to obtain approval to engage in the commercial manufacture, use or sale of thalidomide drug products before the expiration of the '756 and '327 patents, among others, and stating that those patents are invalid, unenforceable, and/or will not be infringed by Barr Laboratories' ANDA

products. Barr Laboratories further admits that Celgene caused the '327 and '756 patent to be listed in the Orange Book prior to the date on which Barr Laboratories filed the ANDA. Barr Laboratories denies the remaining allegations of paragraph 20.

COMPLAINT:

21. No earlier than May 22, 2008, Barr sent written notice of its ANDA amendment to Celgene and CMCC ("Barr's Supplemental Notice Letter"). Barr's Supplemental Notice Letter alleged that the claims of the '327 and '756 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Barr's ANDA. Barr's Supplemental Notice letter also informed Celgene and CMCC that Barr seeks approval to market Barr's Proposed Products before the '327 and '756 patents expire.

RESPONSE : Barr Laboratories admits that on May 22, 2008, Barr Laboratories sent to Celgene and CMCC notice letters of Barr Laboratories' paragraph IV certifications, containing detailed factual and legal statements as to why the '327 and '756 patents are invalid, unenforceable, and/or not infringed by Barr Laboratories' ANDA products. Barr Laboratories further admits that it notified Celgene in those letters that Barr Laboratories seeks FDA approval to engage in the commercial manufacture, use or sale of its ANDA products before expiration of the '327 and '756 patents. Barr Laboratories denies the remaining allegations of paragraph 21.

COMPLAINT:

22. In response, Celgene and CMCC filed this Complaint pursuant to 21 U.S.C. § 355(i)(5)(B)(ii).

RESPONSE : Barr Laboratories admits that Celgene and CCMC have filed this Complaint. Barr Laboratories denies the remaining allegations of paragraph 22.

Count I: Barr's Filing of the ANDA Infringes the '327 Patent

COMPLAINT:

23. Plaintiffs repeat and reallege the allegations of paragraphs 1-22 as though fully set forth herein.

RESPONSE : Barr Laboratories repeats and incorporates by reference its responses to paragraphs 1-22.

COMPLAINT:

24. Barr's submission and amendment of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules, prior to the expiration of the '327 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE : Barr Laboratories admits that its filing of ANDA No. 78-505, containing a paragraph IV certification to the '327 patent, vests this Court with subject matter jurisdiction pursuant to 35 U.S.C. § 271(e) as to that patent. Barr Laboratories denies the remaining allegations of paragraph 24, including any implication that the products that are the subject of Barr Laboratories' ANDA infringe any valid, enforceable claim of the '327 patent.

COMPLAINT:

25. There is a justiciable controversy between the parties hereto as to the infringement of the '327 patent.

RESPONSE : Barr Laboratories admits that there is a justiciable controversy between Celgene, CMCC and Barr Laboratories as to infringement of the '327 patent. Barr Laboratories denies the remaining allegations of paragraph 25.

COMPLAINT:

26. Unless enjoined by this Court, Barr, upon FDA approval of Barr's ANDA, will infringe the '327 patent by making, using, offering to sell, importing, and selling Barr's Proposed Products in the United States.

RESPONSE : Barr Laboratories denies the allegations of Paragraph 26.

COMPLAINT:

27. Celgene and CMCC will be substantially and irreparably damaged and harmed if Barr's infringement of the '327 patent is not enjoined.

RESPONSE : Barr Laboratories denies the allegations of Paragraph 27.

COMPLAINT:

28. Celgene and CMCC do not have an adequate remedy at law.

RESPONSE : Barr Laboratories denies the allegations of Paragraph 28.

COMPLAINT:

29. This case is an exceptional one, and Celgene and CMCC are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE : Barr Laboratories denies the allegations of Paragraph 28.

Count II: Barr's Filing of the ANDA Infringes the '756 Patent

COMPLAINT:

30. Plaintiffs repeat and reallege the allegations of paragraphs 1-29 as though fully set forth herein.

RESPONSE : Barr Laboratories repeats and incorporates by reference its responses to paragraphs 1-29.

COMPLAINT:

31. Barr's submission and amendment of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of thalidomide capsules, prior to the expiration of the '756 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE : Barr Laboratories admits that its filing of ANDA No. 78-505, containing a paragraph IV certification to the '756 patent, vests this Court with subject matter jurisdiction pursuant to 35 U.S.C. § 271(e) as to that patent. Barr Laboratories denies the remaining allegations of paragraph 31, including any implication that the products that are the subject of Barr Laboratories' ANDA infringe any valid, enforceable claim of the '756 patent.

COMPLAINT:

32. There is a justiciable controversy between the parties hereto as to the infringement of the '756 patent.

RESPONSE : Barr Laboratories admits that there is a justiciable controversy between Celgene, CMCC and Barr Laboratories as to infringement of the '756 patent. Barr Laboratories denies the remaining allegations of paragraph 32.

COMPLAINT:

33. Unless enjoined by this Court, Barr, upon FDA approval of Barr's ANDA, will infringe the '756 patent by making, using, offering to sell, importing, and selling Barr's Proposed Products in the United States.

RESPONSE : Barr Laboratories denies the allegations of Paragraph 33.

COMPLAINT:

34. Celgene and CMCC will be substantially and irreparably damaged and harmed if Barr's infringement of the '756 patent is not enjoined.

RESPONSE : Barr Laboratories denies the allegations of Paragraph 34.

COMPLAINT:

35. Celgene and CMCC do not have an adequate remedy at law.

RESPONSE : Barr Laboratories denies the allegations of Paragraph 35.

COMPLAINT:

36. This case is an exceptional one, and Celgene and CMCC are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE : Barr Laboratories denies the allegations of Paragraph 36.

Count III: Inducing Infringement

COMPLAINT:

37. Plaintiffs repeat and reallege the allegations of paragraphs 1-36 as though fully set forth herein.

RESPONSE : Barr Laboratories repeats and incorporates by reference its responses to paragraphs 1-36.

COMPLAINT:

38. Upon information and belief, Barr Pharmaceuticals, Inc. has infringed the '327 and '756 patents under 35 U.S.C. § 271(b) by actively inducing Barr Laboratories, Inc. to infringe the '327 and '756 patents.

RESPONSE : Barr Laboratories states that all claims against Barr Pharmaceuticals, Inc. have been dismissed by the parties' stipulation. Barr Laboratories denies the allegations of paragraph 38.

Prayer for Relief

39. Barr Laboratories incorporates herein by reference its Responses to paragraphs 1-38 of Plaintiffs' Complaint and denies that Plaintiffs are entitled to any relief or judgment against Barr Laboratories or Barr Pharmaceuticals, Inc.

AFFIRMATIVE DEFENSES

First Affirmative Defense

40. Barr Laboratories' 50mg, 100mg, and 200mg thalidomide capsules that are the subject of ANDA No. 78-505 have not infringed, do not infringe, and would not, if marketed, infringe claims of the '327 and/or '756 patents.

Second Affirmative Defense

41. Claims of the '327 and '756 patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

Third Affirmative Defense

42. The '327 and '756 patents are unenforceable due to inequitable conduct before the PTO, as set forth below.

43. On August 22, 1997, Robert D'Amato filed U.S. Patent Application No. 08/918,610 (the "610 application"). Kimberly J. Prior was an attorney who prosecuted the '610 application.

44. On May 22, 2001, the U.S. Patent and Trademark Office issued the '756 patent from the '610 application. The face of the '756 patent names Robert D'Amato as the sole inventor, and the '756 patent is assigned on its face to The Children's Medical Center Corporation ("Children's").

45. On December 15, 1993, Robert D'Amato filed U.S. Patent Application No. 08/168,817 (the "817 application"). Kimberly J. Prior was an attorney who prosecuted the '817 application.

46. On May 13, 1997, the U.S. Patent and Trademark Office issued the '327 patent from the '817 application. The face of the '327 patent names Robert D'Amato as the sole inventor, and the '327 patent is assigned on its face to Childrens Hospital Medical Center Corp. ("Children's").

47. During the prosecution of the '610 application, Prior filed a declaration under 37 C.F.R. § 1.132 on behalf of Shawn Green and a declaration under 37 C.F.R. § 1.132 on behalf of Edward R. Gubish in order to overcome a rejection of the then-pending claims of the '610 Application for lack of enablement under 35 U.S.C. § 112. Green's and Gubish's declarations indicated that Green and Gubish were previously and currently employed by EntreMed, Inc. ("EntreMed").

48. EntreMed and Children's had an extensive relationship during the prosecution history of the '756 and '327 patents. In September 1993, EntreMed entered into an exclusive sponsored research agreement (the "1993 Agreement") to support research conducted under the direction of Dr. Judah Folkman, an employee of Children's, on the role of angiogenesis in pathological conditions. Thalidomide was among the angiogenesis inhibitors under development in accordance with the 1993 Agreement.

49. Under the Agreement, as amended in August 1995, EntreMed agreed to pay Children's $11,000,000 in exchange for the rights to any discoveries from this research. Under the 1993 Agreement as amended, EntreMed also granted to Children's options to acquire 83,334 shares of EntreMed stock and additional options to acquire 50,000 more shares.

50. On June 30, 1999, EntreMed announced the extension of its exclusive sponsored research agreement with Dr. Folkman's laboratory at Children's Hospital in Boston. Under the 1993 Agreement as amended, EntreMed continued to fund research projects in Dr. Folkman's laboratory, including the anti-angiogenic effects of thalidomide, in exchange for the rights to discoveries arising from these projects.

51. On October 1, 1999, EntreMed and Children's entered a further research agreement, listing D'Amato as the principle investigator (the "1999 Agreement"). In this 1999 Agreement, EntreMed agreed to pay Children's $2,000,000 in exchange for rights to the discoveries from this research. The 1999 Agreement indicated that Children's would conduct research related to the Angiogenesis Research Program, which included the testing of thalidomide.

52. As part of the 1993 Agreement, EntreMed obtained an exclusive option to negotiate a license to any technology resulting from the Agreement, which included any potential use of thalidomide to inhibit angiogenesis (the "licensed technology"). EntreMed also received the right to sublicense any licensed technology, including the use of thalidomide to inhibit angiogenesis.

53. In May 1994, EntreMed exercised this licensing option. EntreMed paid aggregated milestone payments of $4,650,000 to Children's, as well as royalties based on sales

of any products developed from the licensed technologies, including the use of thalidomide to inhibit angiogenesis.

54. In December 1995, EntreMed formed a collaboration with Bristol-Myers Squibb ("BMS") to commercialize the licensed technologies, including thalidomide, and gave BMS a right to sublicense those technologies. This collaboration provided for a five year research program, whereby EntreMed agreed to conduct research related to the licensed technologies. As part of this collaboration, BMS agreed to provide $18,350,000 in funding to EntreMed for ongoing thalidomide clinical studies. Also under this collaboration, BMS agreed to pay $730,000 to reimburse EntreMed for ongoing thalidomide clinical studies.

55. Under the collaboration, BMS was granted an exclusive license to the licensed technologies and an equity interest in EntreMed. In exchange, BMS paid EntreMed $1,000,000 in license fees, a portion of which was paid to Children's. Pursuant to this collaboration, BMS also purchased 541,666 shares of EntreMed stock for $12.00 per share in December 1995 and an additional $5,000,000 of EntreMed stock concurrent with EntreMed's June 1996 public offering.

56. On December 9, 1998, EntreMed sublicensed its rights under the Agreement with Children's to Celgene, including the rights related to the use of thalidomide to inhibit angiogenesis as to the '610 application. Gubish electronically executed the sublicense agreement with Celgene on behalf of EntreMed in his capacity as Senior Vice President of Research and Development.

57. EntreMed repeatedly indicated during the prosecution history of the '756 patent that the research related to the use of thalidomide as an inhibitor of angiogenesis, and EntreMed's licensing and sublicensing relationships with Children's related to that research, were important to EntreMed.

58. Green had an extensive relationship with EntreMed and Children's during the prosecution of the '610 and '817 applications, and the '756 and '327 patents. At the time Green submitted his declaration under 37 C.F.R. § 1.132 during the prosecution of the '756 patent, Green was the Senior Director for the Discovery Research/Small Molecule Initiative of EntreMed. Green indicated in his declaration that he previously held various positions at EntreMed, including Senior Scientist, Project Manager, and Director of Cell Biology. Green also indicated in his declaration that he was a member of the Executive Steering Committee for the BMS/EntreMed Alliance for angiogenesis research, and that he supervised this research.

59. During the prosecution history of the '756 patent, Green and D'Amato were co-inventors on patent applications submitted to the U.S. PTO. On March 26, 1998, U.S. Provisional Application No. 60/079,422 (the "'422 application") was filed by Prior. The '422 application lists Green and D'Amato as inventors.

60. On March 26, 1999, U.S. Non-Provisional Application No. 09/277,402 (the "'402 application"), was filed. The '402 application lists Green and D'Amato as inventors.

61. The sole assignee of the '402 application, currently and during the prosecution history of the '756 patent, is listed as Children's. Neither the '402 application nor the '422 application was cited during the prosecution history of the '610 application. Additionally, D'Amato's and Green's status as co-inventors, and the existence of co-pending applications directed to inhibiting angiogenesis with thalidomide, were not disclosed to the PTO. Thus, Green had a substantial relationship with D'Amato that was not disclosed to the PTO.

62. Gubish had an extensive relationship with EntreMed and Children's during the prosecution history of the '610 and '817 applications, and the '756 and '327 patents. At the time Gubish submitted his declaration under 37 C.F.R. § 1.132 during the prosecution of the '756

patent, Gubish was Senior Vice President of Research and Development of EntreMed. Gubish indicated in his declaration that he previously held various positions at EntreMed, including Senior Director of Regulatory Affairs and Vice President of Regulatory and Clinical Development.

63. In December 1998, EntreMed sublicensed its rights under the exclusive sponsored research agreement with Children's to Celgene, including rights to the then-pending '610 application. Gubish executed the sublicensing agreement on behalf of EntreMed. Thus, Gubish had a substantial relationship with Children's that was not disclosed to the PTO.

64. Prosecuting a patent application is an ex parte process and, therefore, the law imposes a duty of good faith, candor, and disclosure on everyone associated with filing and prosecuting the application. See 37 C.F.R. § 1.56; Manual of Patent Examining Procedure § 2000. The duty of candor/disclosure requires, inter alia, the applicant, his or her agents and/or attorneys, and anyone else substantively involved in prosecuting the application to disclose all information that is material to the patentability of the claims.

65. Pursuant to the version of 37 C.F.R. § 1.56 that was in effect prior to 1992, information was defined as "material" for purposes of determining compliance with the duty of candor/disclosure, in part, if "there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent."

66. Pursuant to the version of 37 C.F.R. § 1.56 that was in effect in and after 1992, information was defined as "material to patentability", in part, "when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an

argument of unpatentability relied on by the [PTO], or (ii) Asserting an argument of patentability."

67. Prior and/or D'Amato omitted information that was material to the prosecution of the '756 patent under 37 C.F.R. § 1.56. Based on the above alleged facts, EntreMed and Children's had an extensive relationship during the prosecution history of the '756 and '327 patents in view of the exclusive sponsored research and licensing agreement between EntreMed and Children's. In view of that relationship, EntreMed had a substantial interest in the '610 application and the issuance of the '610 application as a patent. That relationship was material to the prosecution of the '756 and '327 patents. Prior and/or D'Amato knew or should have known about that relationship during prosecution of the '610 and '817 applications, and the '327 and '756 patents. Prior and/or D'Amato withheld the above-identified information concerning that relationship from the PTO during prosecution of the '610 and '817 applications, and the '327 and '756 patents. Prior and/or D'Amato withheld that material information concerning the relationship with the intent to deceive the PTO.

68. Also based on the above alleged facts, Green had an extensive relationship with EntreMed and Children's during the prosecution history of the '756 and '327 patents, in view of the nature of Green's employment with EntreMed and Green's collaborations with D'Amato. In view of that relationship, Green had a substantial interest in the '610 application and the issuance of the '610 application as a patent. That relationship was material to the prosecution of the '756 and '327 patents. Prior and/or D'Amato knew or should have known about that relationship during prosecution of the '610 and '817 applications, and the '327 and '756 patents. Prior and/or D'Amato withheld the above-identified information concerning that relationship from the PTO during prosecution of the '610 and '817 applications, and the '327 and '756 patents. Prior and/or

D'Amato withheld that material information concerning the relationship with the intent to deceive the PTO.

69. Also based on the above alleged facts, Gubish had an extensive relationship with EntreMed and Children's during the prosecution history of the '756 patent, in view of the nature of Gubish's employment with EntreMed and Gubish's direct involvement in licensing agreements involving EntreMed and Children's and licensing agreements involving the '610 application. In view of that relationship, Gubish had a substantial interest in the '610 application and the issuance of the '610 application as a patent. That relationship was material to the prosecution of the '756 and '327 patents. Prior and/or D'Amato knew or should have known about that relationship during prosecution of the '610 and '817 applications, and the '327 and '756 patents. Prior and/or D'Amato withheld the above-identified information concerning that relationship from the PTO during prosecution of the '610 and '817 applications, and the '327 and '756 patents. Prior and/or D'Amato withheld that material information concerning the relationship with the intent to deceive the PTO.

70. Under the provisions of 37 C.F.R. § 1.56 that were applicable during the prosecution of the '756 patent, D'Amato and Prior, as well as other attorneys or agents involved in the preparation or prosecution of the '756 patent, had a duty to disclose to the U.S. PTO material information of which they were aware.

71. An applicant's or its attorney's intentional withholding of information known to be material to patentability with intent to deceive the PTO constitutes inequitable conduct and renders a patent unenforceable.

72. The intentional failure of D'Amato and/or Prior to disclose to the U.S. PTO the above-identified material information concerning the relationships between EntreMed,

Children's, Green and Gubish constitutes a breach of Prior's and D'Amato's duty to disclose information to the U.S. PTO, which, because omitted with deceptive intent, renders the '756 and '327 patents unenforceable.

Fourth Affirmative Defense

73. Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

Fifth Affirmative Defense

74. Barr Pharmaceuticals, Inc. is not a proper party to this action.

Seventh Affirmative Defense

75. Any additional defenses or counterclaims that discovery may reveal.

WHEREFORE, Defendant Barr Laboratories hereby demands judgment dismissing Plaintiffs' Complaint with prejudice, for costs of suit, and for such other relief as the Court may deem just.

COUNTERCLAIMS

For its Counterclaims against Plaintiffs Celgene Corp. and Children's Medical Center Corporation, Barr Laboratories states as follows:

1. On information and belief, Celgene is a corporation organized under the laws of the State of Delaware, with its principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

2. On information and belief, Children's Medical Center Corporation ("CMCC") is a corporation, having a principal place of business at 55 Shattuck Street, Boston, Massachusetts 02115.

3. Barr Laboratories is a wholly owned subsidiary of Barr Pharmaceuticals, Inc., and is organized and existing under the laws of the State of Delaware, having its principal place of business at 223 Quaker Road, Pomona, New York 10970.

Jurisdiction and Venue

4. Barr Laboratories realleges and incorporates by reference the allegations of paragraphs 1-4 of the Counterclaims and paragraphs 1-75 of Barr Laboratories' Answer.

5. Present, genuine and justiciable controversies exist between Celgene and Barr Laboratories regarding the '327 and '756 patents.

6. Subject matter jurisdiction over these counterclaims exists under 28 U.S.C. §§ 1331, 1337, 1338, 1367, 2201 and 2202.

Count I
Declaration of Invalidity of the '327 Patent

7. Barr Laboratories realleges and incorporates by reference the allegations of paragraphs 1-6 of the Counterclaims and paragraphs 1-75 of Barr Laboratories' Answer.

8. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '327 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

9. A present, genuine, and justiciable controversy exists between Celgene, CMCC and Barr Laboratories regarding, inter alia, the validity of claims of the '327 patent.

10. Claims of the '327 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

11. Barr Laboratories is entitled to a declaration that claims of the '327 patent are invalid.

Count II
Declaration of Unenforceability of the '327 Patent

12. Barr Laboratories realleges and incorporates by reference the allegations of paragraphs 1-11 of the Counterclaims and paragraphs 1-75 of Barr Laboratories' Answer.

13. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the '327 patent is unenforceable.

14. A present, genuine, and justiciable controversy exists between Celgene, CMCC and Barr Laboratories regarding, inter alia, the enforceability of the '327 patent.

15. The '327 patent is unenforceable due to inequitable conduct, for the reasons set forth in Barr Laboratories' Third Affirmative Defense, above.

16. Barr Laboratories is entitled to a declaration that the '327 patent is unenforceable.

Count III
Declaration of Non-Infringement of the '327 Patent

17. Barr Laboratories realleges and incorporates by reference the allegations of paragraphs 1-16 of the Counterclaims and paragraphs 1-75 of Barr Laboratories' Answer.

18. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '327 patent will not be infringed by the manufacture, use, or sale of the products described in Barr Laboratories' ANDA No. 78-505.

19. A present, genuine, and justiciable controversy exists between Celgene, CMCC and Barr Laboratories regarding, inter alia, the issue of whether the manufacture, use, or sale of Barr Laboratories' proposed ANDA product would infringe claims of the '327 patent.

20. The manufacture, use, or sale of Barr Laboratories' ANDA products would not infringe claims of the '327 patent.

21. Barr Laboratories is entitled to a declaration that the manufacture, use, or sale of its ANDA products would not infringe claims of the '327 patent.

Count IV
Declaration of Invalidity of the '756 Patent

22. Barr Laboratories realleges and incorporates by reference the allegations of paragraphs 1-21 of the Counterclaims and paragraphs 1-75 of Barr Laboratories' Answer.

23. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '756 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

24. A present, genuine, and justiciable controversy exists between Celgene, CMCC and Barr Laboratories regarding, inter alia, the validity of claims of the '756 patent.

25. Claims of the '756 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

26. Barr Laboratories is entitled to a declaration that claims of the '756 patent are invalid.

Count V
Declaration of Unenforceability of the '756 Patent

27. Barr Laboratories realleges and incorporates by reference the allegations of paragraphs 1-26 of the Counterclaims and paragraphs 1-75 of Barr Laboratories' Answer.

28. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the '756 patent is unenforceable.

29. A present, genuine, and justiciable controversy exists between Celgene, CMCC and Barr Laboratories regarding, inter alia, the enforceability of the '756 patent.

30. The '756 patent is unenforceable due to inequitable conduct, for the reasons set forth in Barr Laboratories' Third Affirmative Defense, above.

31. Barr Laboratories is entitled to a declaration that the '756 patent is unenforceable.

Count VI
Declaration of Non-Infringement of the '756 Patent

32. Barr Laboratories realleges and incorporates by reference the allegations of paragraphs 1-31 of the Counterclaims and paragraphs 1-75 of Barr Laboratories' Answer.

33. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '756 patent will not be infringed by the manufacture, use, or sale of the products described in Barr Laboratories' ANDA No. 78-505.

34. A present, genuine, and justiciable controversy exists between Celgene, CMCC and Barr Laboratories regarding, inter alia, the issue of whether the manufacture, use, or sale of Barr Laboratories' proposed ANDA product would infringe claims of the '756 patent.

35. The manufacture, use, or sale of Barr Laboratories' ANDA products would not infringe claims of the '756 patent.

36. Barr Laboratories is entitled to a declaration that the manufacture, use, or sale of its ANDA products would not infringe claims of the '756 patent.

REQUEST FOR RELIEF

WHEREFORE, Defendant Barr Laboratories respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs Celgene Corp. and Children's Medical Center Corp. as follows:

(a) declaring that the claims of U.S. Patent No. 5,629,327 are invalid, unenforceable and/or not infringed by Barr Laboratories;

(b) declaring that the claims of U.S. Patent No. 6,235,756 are invalid, unenforceable and/or not infringed by Barr Laboratories;

(c) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Barr Laboratories its attorneys' fees, costs, and expenses in this action;

(d) awarding Barr Laboratories any further and additional relief as the Court deems just and proper.

JURY DEMAND

Barr Laboratories demands trial by jury as to all issues so triable.

WINSTON & STRAWN LLP
Attorneys for Defendant Barr Laboratories

By: /s/ James S. Richter
James S. Richter

Dated: August 13, 2008

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, the undersigned counsel for Defendant certifies that, to the best of his knowledge, information and belief, the matter in controversy is not the subject of any other action or proceeding, but is related to the following case, which is a patent infringement action involving one of the same plaintiffs, Celgene Corporation, and the same product, THALOMID®: *Celgene v. Barr Laboratories*, Civil Action No. 07-286 (SDW)(MCA).

/s/ James S. Richter

James S. Richter

Dated: August 13, 2008

CERTIFICATE OF SERVICE

I hereby certify that on August 13, 2008, I served the foregoing **Defendant Barr Laboratories Inc.'s Answer, Counterclaims and Demand for Jury Trial** to the following by ECF and electronic mail:

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